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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

KUBELIK, ANNE R

ART UNIT PAPER NUMBER

1638

DATE MAILED: 11/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/633,274	<b>Applicant(s)</b> PENTAL ET AL.	
	<b>Examiner</b> Anne R. Kubelik	<b>Art Unit</b> 1638	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 6 February 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10,13-16,23 and 33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-10,13-16,23 and 33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 June 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All   b) ☐ Some \*   c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

Art Unit: 1638

### **DETAILED ACTION**

1. The claim numbered 31, submitted on 21 July 2003, has been renumbered claim 33 in accordance with 37 CFR 1.126. Applicant cancelled the original claims 31-32 in the response filed 6 February 2003. Applicant is reminded that claim numbers from cancelled claims are not reused.
2. The amendments of 21 July 2003 have been entered. Claims 1-10, 13-16, 23 and 33 are pending.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Objections***

4. Claim 16 is objected to because of the following informalities:  
Claim 16, part (vi) is missing an article before “marker” and “male”.

### ***Claim Rejections - 35 USC § 112***

5. Claims 1-10 and 13-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Art Unit: 1638

The rejection is modified from the rejection set forth in the Office action mailed 21 April 2003, as applied to claims 1-10, 13-15 and 29. Applicant's arguments filed 21 July 2003 have been fully considered but they are not persuasive.

Applicant urges that all the prior art cited in the prior Office actions require that the skilled worker must know the lethal protein, and its counter or inhibitor protein, while the present invention employs a strategy which does not require any prior knowledge of any counter-protein or its production by the system. Applicant urges that it is for these reasons and to distinguish over the prior art that the phrase was added (response pg 10-12).

This is not found persuasive because there is no indication in the specification that this is envisioned as a limitation to the construct; this is merely listed as an advantage of the construct on pg 24, paragraph 3. Applicant fails to point to support in the specification for the phrase's being envisioned as a limitation to the construct. Furthermore, such a phrase would not allow Applicant to avoid the prior art. It is suggested that the phrase be deleted.

6. Claims 1-10, 13-16, 23 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

The rejection is modified from the rejection set forth in the Office action mailed 21 April 2003, as applied to claims 1-25 and 27-31. Applicant's arguments filed 21 July 2003 have been fully considered but they are not persuasive.

Art Unit: 1638

In claim 1, lines 21-23, “wherein selection ... and” is confusing, and unnecessary. It is suggested that these lines be deleted.

Applicant disagrees for the reasons above (response pg 13). This is not found persuasive this phrase would not eliminate constructs comprising nucleic acids encoding inhibitor proteins and/or regulatory components as prior art - simply not requiring knowledge of these things do not prevent their being present in a construct.

In claim 1, parts (b) and (d), claim 16, the part (d) and the second part (b), and claim 33, parts (b) and (d), is it unclear which host genome is being referred to.

Applicant urges that the phrase refers to the genome of the plant or cell that receives the insulator construct (response pg 14-15). This is not found persuasive; as written with an indefinite article before the first recitation of “host genome”, the phrase means any randomly chosen host. Simply changing “a” to --the-- would create a lack of antecedent basis because the host genome is not defined.

The following rejections are new, based on amendment:

Claim 16, part (iii) lacks antecedent basis for the limitations “the regenerated plants” and “the male sterile plants”.

Claim 16, part (iv) is indefinite in its recitation of “have a single copy of the foreign DNA by Southern hybridization”. It is suggested that “by southern hybridization be moved to after “identifying”.

Art Unit: 1638

Claim 16, part (v) is indefinite in its recitation of “the male sterile plants of step (iv). Which plants are these, the ones use din step (iv) or the ones that have a single copy of the foreign DNA?

Claim 16, part (vi) lacks antecedent basis for the limitation “the male sterile plants that exhibit ...”.

7. Claims 16, 23, and 33 would be allowable if rewritten or amended to overcome the objections and the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

8. Proposed Examiner’s amendments to the claims are attached; these would make the claims allowable.

### ***Conclusion***

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

Art Unit: 1638

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at (703) 308-1098.

Anne R. Kubelik, Ph.D.  
November 3, 2003

A handwritten signature in cursive script that reads "Amy Nelson".

**AMY J. NELSON, PH.D**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**

Art Unit: 1638

***PROPOSED Examiner's Amendment***

Claims 1-2, 16 and 33 are cancelled without prejudice.

In claims 3-5, 7-8 and 10, line 2, claims 6 and 9, line 1, and claim 13, line 3, "1" was replaced with --34--.

In claim 3, line 3, --a gene encoding-- was inserted after "and".

In claim 5, line 3, --a promoter from a gene-- was inserted after "is".

In claim 6, line 2, --from a -- was inserted after "is" and --gene-- was inserted after "TA29".

Claim 23 (amended). The method as claimed in claim [16] 35, wherein [the transformed plant cells of step (i) are generated] step (A) is carried out by *Agrobacterium*-mediated transformation using a disarmed Ti plasmid.

--Claim 34 (new). An insulator construct for reducing leaky expression of a lethal nucleic acid caused by a strong constitutive promoter, wherein the insulator construct comprises:

(i) a first transcription unit comprising in operable linkage: a tapetum specific promoter, a lethal nucleic acid and a transcription termination sequence, wherein said transcription termination sequence comprises a polyadenylation sequence;



Art Unit: 1638

(ii) a second transcription unit comprising in operable linkage: a strong constitutive promoter, a selectable marker nucleic acid and a transcription termination sequence, wherein said transcription termination sequence comprises a polyadenylation sequence;

(iii) an insulator sequence which is about 5 kb in length, wherein the insulator sequence does not:

- (a) comprise any regulatory or enhancer elements;
- (b) produce a functional RNA or protein; or
- (c) cause homology dependent gene silencing of a host gene;

and wherein the insulator sequence is located between the first transcription unit and the second transcription unit so as to reduce leaky expression of the lethal nucleic acid caused by the strong constitutive promoter in the second transcription unit.

Claim 35 (new). A method of producing male-sterile plants of *Brassica juncea*, wherein said method comprises the steps of:

(A) transforming cells of *Brassica juncea* with an insulator construct comprising:

(i) a first transcription unit comprising in operable linkage: a tapetum specific promoter, a lethal nucleic acid and a transcription termination sequence, wherein said transcription termination sequence comprises a polyadenylation sequence;

(ii) a second transcription unit comprising in operable linkage: a strong constitutive promoter, a selectable marker nucleic acid and a transcription termination sequence, wherein said transcription termination sequence comprises a polyadenylation sequence;

Art Unit: 1638

(iii) an insulator sequence which is about 5 kb in length, wherein the insulator sequence does not:

- (a) comprise any regulatory or enhancer elements;
- (b) produce a functional RNA or protein; or
- (c) cause homology dependent gene silencing of a host gene;

and wherein the insulator sequence is located between the first transcription unit and the second transcription unit so as to reduce leaky expression of the lethal nucleic acid caused by the strong constitutive promoter in the second transcription unit;

(B) regenerating transformed plants from the transformed cells;

(C) selecting male-sterile plants from the transformed plants, wherein the male-sterile plants exhibit normal vegetative morphology, normal female fertility, absence of pollen production and failure to set seed on selfing;

(D) selecting from the plants of step (C) male-sterile plants that have a single copy of the insulator construct;

(E) crossing the male-sterile plants from step (D) with untransformed *Brassica juncea* plants to obtain progeny plants; and

(F) selecting from the progeny plants of step (E) plants that exhibit normal seed germination frequencies, normal segregation of the selectable marker nucleic acid, and stable inheritance of male sterility.--